REMARKS

Reconsideration and allowance of the subject application is respectfully requested. By this Amendment, Applicant has canceled claim 41 and added new claim 42. Thus, claims 1-40 and 42 are now pending in the application with claims 13-15, 37 and 38 withdrawn from consideration as being directed to a non-elected invention. Applicant respectfully submits the pending claims define patentable subject matter.

I. Preliminary Matters

The drawings are objected to because the Examiner contends that Figures 10(a), 10(b) and 11 should be labeled "prior art" and the blocks in Figures 1, 2, 3(a), 3(b), 4, 5 and 7 do not have descriptive labels. Applicant is submitting corrected drawings wherein Figures 10(a), 10(b) and 11 are labeled "prior art", and the blocks in Figures 1, 2, 3(a), 3(b), 4, 5 and 7 have been provided with descriptive labels in accordance with their description in the specification (e.g., 116 - microprocessor, 115 - charging circuit, etc.). Accordingly, the Examiner is requested to remove the objection to the drawings.

The specification is objected to because the Examiner maintains that the "wording of the first paragraph on page 8 and the third paragraph on page 9 is awkward." Further, the abstract is objected to because the Examiner asserts that the "abstract describes different circuits used to deliver the phases of the waveform and does not provide a general overview of the invention." By this Amendment, Applicant has amended specification and abstract to improve clarity. Accordingly, the Examiner is requested to remove the objections to the specification and abstract.

II. Rejection of claims 9, 39 and 41 under 35 U.S.C. § 112, second paragraph

Claims 9, 39 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

With regards to claim 9, the Examiner contends that the claim "is unclear because the circuits claimed do not correspond with the specification and the figures." In particular, the Examiner appears to be asserting that claim 9 is indefinite because the claim does not claim more than one inductor and does not claim second and third switching means.[1] However, there is no requirement in 35 U.S.C. § 112 or anywhere else in the patent law that a claim contain all of elements pertaining to a particular embodiment disclosed in the specification. That is, there is no statutory provision which allows the Examiner to force the Applicants to limit their claims to a particular arrangement of components describing and picturing a preferred embodiment of the invention. Accordingly, Applicant respectfully submits that claim 9 is both definite and entirely proper under 35 U.S.C. §112, since those of ordinary skill in the art can easily ascertain the metes and bounds of the present invention from the pending claim.[2]

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[1] Claim 11 (which depends from claim 9) further defines the claimed invention by reciting the second and third switching means.

[2] The first sentence of the second paragraph of 35 U.S.C. § 112 requires only that claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity." In the absence of evidence to the contrary, what the claim defines is what the applicant regards as his invention. If those skilled in the art can tell whether and particular embodiment is within the scope of a claim, the claim fulfills its purpose as a definition. See *In re Miller*, 169 U.S.P.Q. 597 (CCPA 1971).

With regards to claim 39, the Examiner asserts that the phrase "an external type" is unclear. With regards to claim 41, the Examiner asserts that the phrase "repeating a plurality of times" is unclear. By this Amendment, Applicant has amended claims 39 and 41 to improve clarity.

In view of the above, the Examiner is requested to remove the § 112, second paragraph, rejection .

III. Prior Art Rejections

A. Disclosure of Lyster

Lyster is directed to a damped biphasic energy delivery circuit for a defibrillator. As shown in Figures 2 and 3, a defibrillator includes an energy storage circuit 20 coupled across a high voltage switch 28 such as an H-bridge for delivering a defibrillation pulse to the patient through a pair of electrodes 16. A battery 24 provides power for the defibrillator 10 in general and in particular for a high voltage charger 22 which charges the capacitors in an energy storage circuit 20. Typical battery voltages are 12 volts or less, while the energy storage circuit 20 may be charged to 1500 volts or more. A charge voltage control signal from the controller 26 determines the charge voltage in the energy storage circuit 20. A controller 26 operates to control the entire defibrillation process and detects shockable rhythms from the patient via an ECG front end 18. The energy storage circuit 20 consists of an energy storage capacitor 50, a series inductor 54, a shunt diode 58, and a resistor 56 in series with the inductor. The controller 26 measures as the patient dependent parameter the time interval between the initial delivery of the defibrillation pulse and the occurrence of the peak current or voltage to determine the first and

second phases of the defibrillation pulse to provide for compensation for patient impedance. Other types of patient dependent parameters, measured either before or during delivery of the DBT defibrillation pulse, could be alternatively employed to achieve the impedance compensation.

B. Disclosure of Morgan

Morgan is directed to a cardiac defibrillator including an electronic energy transfer circuit. As shown in Figure 1, the cardiac defibrillator 10 includes an energy transfer circuit 40 for delivering a cardiac defibrillation pulse to a patient from an energy storage capacitor 16. A control circuit 20 transmits a shock signal to the energy transfer circuit 40 which causes the energy transfer circuit 40 to transmit a cardiac defibrillation pulse to a patient 50.

As shown in Figure 2, the energy transfer circuit 40 includes a solid state switch 42, a current shunt 56 and a pair of spark gaps 46a and 46b. The solid state switch 42 has an input terminal 42a connected to energy storage capacitor 16, a control input terminal 42b coupled to the control circuit 20 and an output terminal 42c connected to a patient path 44 that includes the patient 50. The pair of spark gaps 46a and 46b are connected in series with the pair of patient electrodes 52a and 52b and the patient 50, wherein electrical current flows across the spark gaps 46a and 46b when a sufficiently high voltage signal is applied to them. A current shunt 56 is placed in parallel with the patient path 44 to divert the leakage current away from the patient path until a defibrillation pulse is delivered. A current sensor 64 or a voltage sensor 72 may be

provided to generate a feedback signal which is provided to the control circuit 20 to regulate the energy of the defibrillation pulse that flows through the patient.

C. Disclosure of Cameron

Cameron is directed to an electrotherapy method and apparatus for delivering a multiphasic waveform from an energy source to a patient. As shown in Figures 3 and 4, the defibrillator system 30 comprises an energy source 32 to provide a voltage or current pulse, and a connecting mechanism 34 which selectively connects and disconnects a pair of electrodes 36 electrically attached to a patient 37 to and from the energy source. The defibrillator system is controlled by a controller 38 which operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36.

The controller 38 receives discharge information (such as current, charge and/or voltage) from the discharge circuit and timing information from a timer 40. The controller 38 uses information from the discharge circuit and/or the timer to control the shape of the waveform delivered to the patient in real time (i.e., during delivery of the waveform), such as by selecting appropriate waveform parameters from a memory location associated with the controller or by otherwise adjusting the duration of the phases of the biphasic waveform. By controlling the waveform shape, the system controls the duration, tilt and total delivered energy of the waveform. The connecting mechanism 34 includes four switches 56, 58, 60 and 62 operated by the controller 38 to deliver a shock from the energy source 32 to the patient. A current limiting

circuit comprising a resistor 64 and switch 66 provides additional protection to the defibrillator circuit components and to the defibrillator operator.

D. Analysis

Claims 1-12, 36 and 39-41 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lyster et al. (U.S. Patent No. 6,405,081; hereafter "Lyster"). Claims 1-12, 36 and 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan et al. (U.S. Patent No. 5,222,492; hereafter "Morgan") in view of Cameron et al. (U.S. Patent No. 5,607,454; hereafter "Cameron"). Applicant respectfully traverses the prior art rejections.

With regards to the § 102(e) rejection, the Examiner generally alleges that Lyster discloses all of the features of invention recited in independent claims 1 and 2 without specifically identifying which elements of Lyster's defibrillator correspond to the claimed means.

With regards to the § 103(a) rejection, the Examiner maintains that Morgan discloses all of the features of the invention recited in independent claims 1 and 2 except for the waveform being biphasic/multiphasic and means for reversing the polarity of the voltages outputted to the output electrode. However, the Examiner generally alleges that these features are disclosed by Cameron.

Applicant respectfully submits the claimed invention would not have been anticipated by or rendered obvious in view of the cited references. In particular, Applicant submits the cited references do not teach or suggest the claimed "means for reversing polarity of the voltage

outputted to the output electrode, and outputting at least first phase waveform and second phase waveform to the output electrode".

It is well settled that 35 U.S.C. § 112, sixth paragraph, requires that (1) the prior art element perform the identical function specified in the means plus function limitation, and (2) the prior art element's structure must be the same as or equivalent to the structure corresponding to the claimed means. This rule of law is reflected in MPEP 2182, which reads:

> *If a prior art reference teaches identity of function to that specified in a claim, then ... an examiner carries the initial burden of proof for showing the prior art structure ... is the same as or equivalent to the structure ... corresponding to the claimed means ....* (Applicants' emphasis).

However, the rejection grounds have not correctly followed this straightforward guidance.

Lyster, Morgan and Cameron each disclose utilizing a conventional H-bridge circuit formed by four switches to reverse the polarity of the output waveform. On the other hand, the present application teaches utilizing three switches for reversing the polarity of the output waveform. That is, as shown in Figure 1, a positive polarity of the electric energy storage section 104 is connected to an inductor 105 through a switch 101 (the first switch means), and further, the opposite side terminal of the inductor 105 is connected to a negative polarity of the electric energy storage section 104 through a switch 103 (the third switch means). The opposite side terminal of the inductor 105 is connected to the one output electrode 112a to apply an electric stimulation pulse onto the patient 113 (the impedance of the patient is 113a) through a switch 102 (the second switch means), through the inductor 110.

Thus, while Lyster and Cameron disclose switching circuits which may perform a function similar to that of set forth in the claimed means limitation (i.e., reversing polarity of the voltage outputted to the output electrode, and outputting at least a first phase waveform and a second phase waveform to the output electrode), the rejection position is incorrect since the cited references do not disclose the same or equivalent structure.

MPEP 2183 (A) provides guidance for determining whether the prior art element is an equivalent, which requires that:

> *the prior art element performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification.* (Applicants' emphasis).

Since an analysis consistent with this guidance shows that structure of Lyster and/or Cameron is not an equivalent, Applicant respectfully submits that the claims 1-12, 36 and 39 should be allowable over the cited references.

By this Amendment, Applicant has amended independent claim 40 to further define the claimed method. In particular, amended claim 40 recites "delivering the necessary electric energy within a predetermined time period from the remaining energy in a second phase waveform , wherein a shape of the second phase waveform is arbitrarily controlled within a range of energy remaining in the electric energy storage section."

In addition, Applicant has added new method claim 42 which recites "delivering a necessary electric energy in a first phase waveform; and delivering a necessary electric energy from the electric energy remaining in the electric storage section in a second phase waveform and the first phase waveform which are alternately repeated at least once, wherein a shape of the

first phase waveform and a shape of the second phase waveform are arbitrarily controlled at the step of delivering the necessary electric energy from the electric energy remaining in the electric storage section."

Applicant respectfully submits that the combined references do not teach or suggest thes features of claims 40 and 42.

In the conventional H-bridge circuit (utilizing four switches) of Lyster, Morgan and Cameron, the waveform of an output signal must be a truncated exponential waveform. Although Lyster teaches the peak voltage of the output signal is restricted by using the inductor 54 shown in Fig. 3, the output voltage attenuates in accordance with a predetermined time constant such that Lyster also teaches the truncated exponential waveform.

The output voltage of the truncated exponential waveform is naturally determined by a duration, a capacitance of a condenser and an impedance of a load (including the inductance in Lyster). In a configuration using the conventional H-bridge circuit, only a duration of the output signal is positively controlled. The outputted energy is naturally determined in accordance with the duration.

In the present invention, as shown in Figs. 6(a)-6(d), the second phase waveform can be controlled arbitrarily within a range of energy remaining in the electric energy storage section (capacitor 104). Specifically, a reference curve (e.g., Figs. 8(a) and 8(b)) is set to determine a time-dependent variation of an on/off duty of the first switch means, so that the output waveform is thus determined. The shape of the reference curve is arbitrary. Even if the duration of the

second phase waveform is fixed, the output voltage during the duration can be arbitrarily controlled in accordance with the method of the present invention.

Further, in a case where the duration of the stimulation pulse is fixed, the energy supplied by the truncated exponential waveform is limited in accordance with the living body impedance. When the living body impedance becomes small, the supplied energy becomes large, and vice versa.

The present invention teaches a power-constant waveform as one of arbitrary waveforms to be output. In this case, although the duration of the stimulation pulse is fixed, the constant energy can be supplied to a living body within the duration, irrespective of the impedance value of the living body.

Accordingly, Applicant respectfully submits that claims 40 and 42 should be allowable because the cited references do not teach or suggest all of the features of the claims.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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